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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,194	07/31/2003	Ping Gao	01259/2/US	3162

26648 7590 08/03/2007

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EXAMINER
LAO, MARIALOUISA

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
08/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,194	GAO, PING	
	Examiner	Art Unit	
	M. Louisa Lao	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-23,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-23,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Argument

1. The applicants' arguments and amendments to the claims in the reply dated June 14, 2007 have been considered, as follows:

a) the rejection of claims 19, 22, 23 under 35 USC§112 2nd¶ is withdrawn and the cancellation of claims 30-31 is acknowledged.

b) the amendments to claims 19, 22, 23 and 32 are acknowledged.

c) the rejection of claims 19-23 and 30-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 14, 25-28 and 32-33 of copending Application No. US2004/01015883, US `883 (SN10/633390) and over claims 19-21, 23 and 26-31 of copending Application No. US2004/0131670, US`670 (SN10/633102), is withdrawn; since these copending applications have been abandoned.

d) the rejection of claims 19-23 and 30-33 under USC 102 over claims 1, 4, 6-8, 14, 25-28 and 32-33 of copending Application No. US2004/01015883, US `883 (SN10/633390) and over claims 1, 3 10, 11, 21-24 and 28-29 of copending Application No. US2004/0105884, US`884 (SN10/632737), is withdrawn.

Provisional Obviousness-Double Patenting Rejection

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **The provisional rejection of claims 19-23 and 30-33 is maintained** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 10, 11, 21-24 and 28-29 of copending Application No. US2004/0105884, US`884 (SN10/632737).

4. The instant claims are drawn to a pharmaceutical dosage form comprising a fill material sealed in capsule shells, wherein the capsule shells comprise a sulfite compound, and wherein said sulfite compound is present in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells and the fill material comprises celecoxib.

5. US`884 discloses a pharmaceutical dosage form comprising a fill material sealed in capsule shells wherein the fill material comprises a drug, which is celecoxib and at least one sulfite compound, wherein the capsule shells comprise gelatin and the sulfite compound is in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells.

6. The instant claims anticipate US`884, since the instant claims recite the fill material is celecoxib, a pharmaceutical drug, which is the drug in US`884 and all the parameters of the gelatin capsule and constituents thereto.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **The rejection of claims 19-20, 22-23 and 30-32 is maintained** under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (EP0695544, EP `544) and further in view of Berthel et al. (US2003/0219477, US`477).

11. The instant claims are drawn to a pharmaceutical dosage form comprising a fill material sealed in capsule shells, wherein the capsule shells comprise a sulfite compound, and wherein said sulfite compound is present in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells and the fill material comprises celecoxib.

12. EP `544 discloses gelatin capsules that are resistant to denaturation with the use of free radical scavengers, which are exemplified *inter alia* by pharmaceutically acceptable sulfites and hydrogen sulfites. See page 2 lines 10-17, page 3 under Example 1 and claim 4.

EP `544 teaches that the "...generation of aldehyde is suppressed and as a result the formulation of a thin film on the gelatin capsules and insolubilization are inhibited even though PEG and the like are used as fillers." See page 3 lines 37- 43.

EP`544 does not disclose the fill material is the drug celecoxib.

13. However, US`477 discloses in page 9 claims 6, 10, 13 and 16 a pharmaceutical soft gelatin capsule in unit dosage form with a filling comprising a drug, which is *inter alia,* celecoxib.

14. It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to substitute the drug celecoxib into the fill material of EP`544 since US`477 discloses the same type of gelatin capsule as that used in EP`544.

15. One having ordinary skill in the art would have been motivated to substitute the drug celecoxib into the fill material of EP`544 since this drug was disclosed by US`477 as a suitable fill material in a gelatin capsule and the artisan would have expected a reasonable degree of success with this substitution.

16. **The rejection of claims 19-20, 22-23 and 30-33 is maintained** under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (EP0695544, EP `544) and further in view of Berthel et al. (US2003/0219477, US`477) and Black et al. (USPatent 5,733,909, US `909).

17. The instant claims are drawn to a pharmaceutical dosage form comprising a fill material sealed in capsule shells, wherein the capsule shells comprise a sulfite compound, and wherein said sulfite compound is present in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells and the fill material comprises celecoxib.

18. EP `544 art discloses gelatin capsules that are resistant to denaturation with the use of free radical scavengers, which are exemplified *inter alia* by pharmaceutically acceptable sulfites and hydrogen sulfites. See page 2 lines 10-17, page 3 under Example 1 and claim 4.

Further, the EP `544 art teaches that the "...generation of aldehyde is suppressed and as a result the formulation of a thin film on the gelatin capsules and insolubilization are inhibited even though PEG and the like are used as fillers." See page 3 lines 37- 43.

19. EP`544 does not disclose the fill material is the drug celecoxib.

20. However, US`477 discloses in page 9 claims 6, 10, 13 and 16 a pharmaceutical soft gelatin capsule in unit dosage form with a filling comprising a drug, which is *inter alia,* celecoxib.

21. Neither EP`544 nor US`477 disclose the amine compound in the soft gelatin capsule.

22. However, US`909 teaches a pharmaceutical composition for treating COX-2 medicated diseases comprising a particular drug of low water solubility, the selective COX-2 inhibitor having the formula (I) therein, the particular solvents such as polyethylene glycol (PEG), water and organic amine such as tertiary amine or diethanolamine. See abstract, column 1 lines 45-67;

see column 8 lines 10-15. Further, the USPatent `909 teaches that the pharmaceutical composition therein is in the form of a capsule or an imbibable liquid to be administered orally. See column 9 line 66 to column 10 lines 1-67.

23. US`909 discloses in column 8 lines 1-55 the various types of amine compounds that are present with COx-inhibitory drugs. While in column 12 lines 25-28, US`909 discloses that the dosage unit forms generally contain 1mg to 500mg of an active ingredient (i.e. COx-inhibitory drugs).

24. It would have been obvious for the artisan skilled in the art at the time of the invention, to utilize an amine compound in the gelatin capsule of EP`544 utilizing the fill material of US`477 since the pharmaceutical composition of US`909 can also be used as a fill material in gelatin capsules, which are equivalent to the gelatin capsules of EP`844 and US`477.

25. One having ordinary skill in the art would have been motivated to incorporate the amine compound disclosed in US`909 since the amine compound with a drug in a pharmaceutical composition as that disclosed by US`477 and EP`544, the nature of which are similar and drawn to equivalent therapeutic drugs, like celecoxib, in a gelatin capsule shell, incorporating at least a sulfite compound which is a cross-linking and/or pellicle inhibitor, will allow the artisan to arrive at a reasonable expectation of success.

26. As to the recitation of **claim 21** of self-emulsification of the fill material upon contact with gastric fluid, the examiner takes the position that this characteristic of self-emulsification is known by a person of ordinary skill in the art at the time of the invention that pharmaceutical compositions used as fill materials for gelatin capsules, composed of oils, surfactants and excipients, as recited in the instant application ***would inherently*** behave as a o/w (oil-in-water)

emulsions upon contact with fluids of the GIT (gastric-intestinal tract). It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. "Under the principle of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHK/Biophile Int'l corp. V. Miltraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305.*

27. **Thus, the instant application, as amended, is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made since the combined teachings of the prior art suggest the instant application.**

Response to Arguments

28. Applicant's arguments filed 6/14/07 have been fully considered but they are not persuasive. Applicants amended claims to delineate the sulfite compounds in the capsule shells therein, inclusion of amine compound and sulfite compounds in the fill material. Applicants argue that none of the cited references, EP'544 or US`477 or US`909, recite or describe "dosage forms" comprising sodium metabisulfite, sodium bisulfite, or sodium thiosulfate. However, US`909 profusely discloses the term "dosage forms", see columns 9-11, where the dosage forms are discussed extensively. The examiner further takes the stand that the gelatin capsule, by the very nature of its inception, *is* a dosage form. The combined teachings of the cited prior art references, therefore, still read on the instant claims, as amended. Further, the KSR caselaw forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness.

29. Further, the art rejection and provisional obviousness double-patenting rejection has not been obviated by the amendments to the claims, and the rejection stands.

30. There are no allowable claims.

31. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Thursdays from 8:00am to 8:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

`mll07302007
MLouisa Lao
Examiner
Art Unit 1621

for YVONNE EYLER
SUPERVISORY PATENT EXAMINER
TC1600 GAU 1621